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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,927

09/13/2006

Stephen Martone

386/05062

1141

44909

7590

09/14/2009

PRTSI

P.O. Box 16446

Arlington, VA 22215

EXAMINER

NGUYEN, TINA MY PHUONG

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,927	<b>Applicant(s)</b> MARTONE ET AL.	
	<b>Examiner</b> TINA NGUYEN	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
3. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I, claim(s) 1-23**, drawn to a sheath assembly with an internal sheath and at least one channel tube external to the internal sheath, the channel tube being foldable.

**Group II, claim(s) 24-29**, drawn to an invasive tool with a probe and a flexible channel tube, the channel tube being foldable to an open or closed state, normally held in a closed state.

**Group III, claim(s) 30-32**, drawn to a channel add-on comprising a channel tube which is foldable into a closed state and means for opening the tube into the open state.

**Group IV, claim(s) 33-42**, drawn to a method of providing an endoscopic channel, including the steps of inserting into the patient a probe with a sheath assembly including a foldable channel tube which is in its closed state, and then opening the tube into the open state.

**Group V, claim(s) 43-50**, drawn to a sheath assembly with an internal sheath and an external sheath, the internal and external sheaths being directly connected to each other.

**Group VI, claim(s) 51-55**, drawn to a sheath assembly comprising an intermediate sheath which defines a first channel between the probe and intermediate sheath, and an external sheath which defines a second channel between the intermediate sheath and the external sheath.

**Group VII, claim(s) 56-60**, drawn to a sheath assembly for a probe comprising an internal sheath and a channel tube with variable transverse extent, and a nozzle connected to the distal end of the channel tube.

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**Group VIII, claim(s) 61-66**, drawn to a sheath assembly with an internal sheath and a channel tube with a variable transverse extent, channel tube not having an aperture at its distal end.

**Group IX, claim(s) 67-72**, drawn to a method of inserting a working tube into a channel comprising providing a guide wire within the channel and inserting the working tube into the channel along the guide wire while the channel is within a patient.

4. The inventions listed as Groups I--IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

5. The technical feature founded in **Groups I-IX** do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature in Groups I-IV is a channel tube with a collapsible channel in a sheath assembly. The technical feature in Group V is a sheath assembly with an internal and external sheath, the two sheaths being directly connected to each other. The technical feature in Group VI is a sheath assembly with an internal and external sheath. The technical feature in Group VII is a variable transverse extent channel tube with a nozzle connected to the distal end of the channel tube. The technical feature in Group VIII is a variable transverse extent channel tube without an aperture at its distal end. The technical feature in Group IX is inserting the working tube into a channel containing a guide wire. These groups therefore lack a common special technical feature and hence, a holding that these groups do not have a single general inventive concept is proper.

6. The technical feature founded in **Groups I-IV** is a channel tube with a collapsible channel in a sheath assembly. This element cannot be a special technical feature under PCT rule 13.2 because the element is shown in the prior art. Nakao et al. (U.S. Patent 5,217,001) disclose a sheath assembly with a main internal channel and surrounding biopsy channels which are expanded from collapsed position (Abstract, Fig. 5). Therefore, this feature cannot be a special technical feature under PCT Rule 13.2 because it fails to provide contribution to the prior art.

7. A telephone call was made to Martin Moynihan on 08/31/09 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TINA NGUYEN whose telephone number is (571)270-1489. The examiner can normally be reached on M-Thurs 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/  
Supervisory Patent Examiner, Art  
Unit 3739

/T. N./  
Examiner, Art Unit 3739  
8/31/2009